UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND, and ALLIED SERVICES DIVISION WELFARE FUND on behalf of themselves and all others similarly situated,

Plaintiffs,

-against-

SANOFI-AVENTIS U.S. LLP, and SANOFI-AVENTIS U.S., INC.

Defendants.

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REPORT & RECOMMENDATION

08-CV-0179 (SLT) (RER)

RAMON E. REYES, JR., U.S.M.J.:

INTRODUCTION

Plaintiffs Sergeants Benevolent Association Health and Welfare Fund ("SBA Fund"), New England Carpenters Health Benefits Fund ("NEC Fund"), and Allied Services Division Welfare Fund ("ASD Fund") (collectively "Plaintiffs") allege that defendants Sanofi-Aventis U.S. LLP and Sanofi-Aventis U.S., Inc. (collectively "Aventis") fraudulently marketed the prescription drug Ketek by misrepresenting its safety and efficacy. Plaintiffs bring claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c) (Count I) and § 1962(d) (Count II), forty-four state consumer protection statutes (Count III), and unjust enrichment (Count IV). (Docket No. 11, Second Amended Class Action Complaint ("Sec. Am. Compl.") ¶¶ 73, 88, 97, 98-41, 150.) Plaintiffs seek to certify a nationwide class of all third-party payors who paid or incurred costs for Ketek prescriptions between April 1, 2004 and February

12, 2007, for the drug's uses other than for community-acquired pneumonia. On May 6, 2010, the Honorable Sandra L. Townes referred this matter to me for a report and recommendation. (Docket No. 113.)

For the reasons explained below, I respectfully recommend that Plaintiffs' motion for class certification be denied.

BACKGROUND[1]

I. Ketek's Path to FDA Approval

Telithromycin is a prescription antibiotic developed and marketed by Aventis under the brand-name Ketek. (Sec. Am. Compl. ¶¶ 5, 6, 10.) On February 28, 2000, Aventis submitted a New Drug Application ("NDA") to the Office of New Drugs at the United States Food and Drug Administration ("FDA"), seeking approval to sell Ketek in the United States. (Sec. Am. Compl. ¶ 12.) The NDA sought Ketek's approval for acute bacterial sinusitis ("ABS"), acute exacerbation of chronic bronchitis ("AECB"), community-acquired pneumonia ("CAP"), and tonsillopharyngitis.[2]

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[1] Except where otherwise indicated, these background facts are taken from the Proffer of Facts in Support of Plaintiffs' Motion for Class Certification ("Pl.s' Proffer").

[2] A drug manufacturer seeking FDA approval to market a new prescription drug in the United States must first submit an Investigational New Drug application ("IND") to the FDA. (Defendants' Response to Plaintiffs' Factual Proffer at ¶ 10 ("Defs' Resp. Proffer").) On February 19, 1998, Aventis submitted an IND application to the FDA for Ketek listing the indications (the same four indications in Aventis's NDA) that Aventis sought to investigate the safety and efficacy. (Ex.134 at 03202045.) On March 20, 1998, the IND became effective, and Aventis began shipping Ketek to clinical investigators to study its effects on humans and begin the process for approving its sale and marketing in the United States. (Pl.s' Proffer at 19.)

On April 26, 2001, the FDA's Anti-Infective Drug Advisory Committee ("the Committee") recommended limited approval of Ketek only for treating CAP and recommended the collection of more efficacy and clinical safety data from a larger patient sample. (Pl.s' Proffer at 23–24.) On May 18, 2001, Aventis met with the FDA's division of Anti-Infective Drug Products to discuss the FDA's upcoming approval decision, as well as how to design and define study protocols. (Pl.s' Proffer at 24.) As the Committee was meeting and determining recommendations, the FDA's Center for Drug Evaluation and Research completed its review of Aventis's first submission in support of its Ketek NDA. (*Id.*) That review found "significant concerns regarding the hepatotoxic potential of telithromycin." (*Id.* at 24–25.)

"On June 1, 2001, the FDA issued the first Approvable Letter for the use of Ketek on CAP, AECB, and ABS pending the review of additional efficacy and safety data . . . before the FDA would approve Ketek for sale and marketing for the three indications, it required Aventis to show more evidence on the drug's safety and efficacy." (Pl.s' Proffer at 28.)[3]

II. Study 3014

In October 2001, Aventis hired Pharmaceutical Product Development, Inc. ("PPD"), a contract research organization, to monitor Study 3014, a large comparative study created to address the FDA's concerns regarding adverse events and assess Ketek's safety and efficacy when used to treat community-acquired respiratory tract infections. (Pl.s' Proffer at 28–29.) Early in the course of its evaluation, PPD alerted Aventis to concerns it had with the integrity of data from several trial sites in Study 3014, specifically with the office of Dr. Marie Anne

[3] The FDA has since revised its regulations so that as of August 11, 2008, it no longer issues "approvable" letters. (Docket No. X [CONFIDENTIAL], Defs' Resp. Proffer ¶ 13, n.36.)

Kirkman Campbell, which treated the largest number of patients in the study. (Pl.s' Proffer at 31.)

On July 24, 2002, Aventis filed a complete response to the FDA's Approvable Letter and resubmitted its NDA, including data from Phase I studies, clinical efficacy data from four Phase III studies, post-marketing safety data from other countries, and safety data from Study 3014. (Pl.s' Proffer at 41.)

On October 15, 2002, an investigator from the FDA's Division of Scientific Investigations began inspecting Dr. Kirkman Campbell's office. (Pl.s' Proffer at 44.) Aspects of Study 3014 were reported to the FDA's Office of Criminal Investigation ("OCI"), which in turn reported these preliminary findings to the United States Attorney before widening inspections to other offices with high numbers of enrolled patients.[4] (Sec. Am. Compl. ¶¶ 17–19.) The OCI found misconduct and protocol violations at several other sites with high patient enrollment. (Pl.s' Proffer at 38–39.)

In January 2003, the Office of New Drugs again declined to approve the NDA for Ketek, requesting more information on Study 3014 and additional safety evidence. (Sec. Am. Compl. ¶ 23.) In July 2004, Aventis submitted a report without any caveats about that study's integrity and stated that the "study was conducted in accordance with good clinical practice and Aventis standard operating procedures for clinical investigation and documentation." (Sec. Am. Compl. ¶ 26.) According to Plaintiffs' expert, "Aventis claimed Ketek's safety and efficacy profile matched that of other antibiotics . . . Aventis[] (I) concealed the scientific fact that Study 3014

[4] On April 29, 2003, the federal government indicted Dr. Kirkman Campbell on multiple fraud counts. She pleaded guilty and was sentenced to a term in prison for fraud in conducting the Ketek study. (Defs' Resp. Proffer at ¶ 25.)

actually showed that Ketek was almost three times more likely to result in a possibly medication-related, serious adverse event; (ii) knew that Ketek was neither more efficacious nor as safe as widely available alternatives; and (iii) knew that claims that Ketek did better against antibiotic resistant pathogens were not scientifically supported." (Plaintiffs' Memorandum In Support Of Class Certification at 3, nn.10–14 ("Pl.s' Mem."), citing Ex. 4: Report of John David Abramson.)

On January 8, 2003, the Committee met for a second time to discuss Ketek. (Defs' Resp. Proffer at 14.) The parties dispute whether the FDA or Aventis was responsible for withholding information about the integrity of Study 3014 from the Committee. (Pl.s' Proffer at 52) (Defs' Resp. Proffer at ¶ 29.) The FDA did not accept the Committee's recommendation to approve Ketek for AECB, ABS, or CAP, choosing instead to continue investigating the good clinical practices violations and data reliability issues in Study 3014. (Defs' Resp. Proffer at ¶¶ 29, 30.) On January 24, 2003, the FDA sent a second Approvable Letter to Aventis requesting additional information about Study 3014, additional analysis of the findings of Study 3014 and the Phase III studies, and additional information from the postmarketing safety reports from other countries where Ketek had been approved and was in use. (Defs' Resp. Proffer at ¶ 30.)

III. FDA Approval and Subsequent Marketing

On April 1, 2004, Ketek ultimately received FDA approval for three indications: ABS, AECB, and CAP. (Pl.s' Proffer at 66.) The parties dispute whether the FDA relied on epidemiological conclusions from Study 3014 to support its decision to approve Ketek. (Pl.s' Proffer at 58–59) (Defs' Resp. Proffer at ¶¶ 36–37.) Aventis did not include any warning about

hepatic events beyond the general reference to hepatic events in the Precautions section. (Pl.s' Proffer at 66–67.)

In April 2004, Ketek entered the United States market and Aventis launched a marketing campaign designed to expand its market share across all anti-microbial drugs. (Sec. Am. Compl. ¶¶ 30-31.) "To achieve a sizeable portion of the RTI market share, Ketek would face extensive competition from established medications like Zithromax, Augmentin, Ceftin, Cipro, Levaquin and others." (Pl.s' Proffer at 20.) Aventis promoted Ketek as having valid regulatory approval for all three of its indications, being as safe and more effective than other antibiotics, and being comparatively less likely to induce antibiotic resistance. (Pl.s' Proffer at Sec. VI(B).) Early on, Ketek sales grew exponentially; from its mid-2004 launch until January 2006, Ketek "experienced explosive growth in this 'promotionally sensitive' antibiotics market, grossing $209 million in 2005." (Pl.s' Proffer at 1.) Aventis marketed Ketek to TPPs, which gave Ketek preferred treatment on formularies. (Plaintiffs' Reply Memorandum of Law In Further Support of Class Certification at 2 ("Pl.s' Reply"), Ex. 379, Rosenthal Rebuttal Decl., Figs. 1.a & 1.b.) Aventis' Ketek marketing caused its early rise in usage. (Pl.s' Proffer at 1.) In 2005, Ketek was prescribed over 3 million times in the United States; and by 2006 Ketek sales surpassed 6.1 million prescriptions. (Sec. Am. Compl. ¶ 33.)

Ketek sales began to drop in January 2006, after the FDA released a public health advisory that warned physicians to monitor Ketek patients for potential liver problems. (Pl.s' Proffer at 80.) By June 2006, "[twenty-three] cases of acute severe liver injury and [twelve] cases of acute liver failure, [four] of them fatal, had been linked to Ketek. By the end of 2006, Ketek had been implicated in [fifty-three] cases of hepatotoxic effects." (Pl.s' Proffer at 81.) On

June 29, 2006, Aventis changed Ketek's label to include additional warnings, precautions, contraindications, and adverse reactions pursuant to FDA requirements. Aventis also sent letters to healthcare professionals about these risks.

The withdrawal of FDA's approval for Ketek's indications for sinusitis and bronchitis became effective on February 9, 2007. (Pl.s' Proffer at 84.)

IV. The Role of Third-Party Payors

SBA Fund, NEC Fund, and ASD Fund are employee health and welfare benefit funds who, as third-party payors ("TPPs"), provide health care benefits to covered lives in their membership. (Sec. Am. Compl. ¶¶ 2–4.) Most TPPs that provide prescription drug benefits contract with pharmacy benefit managers ("PBMs") to administer these benefits.[5] (Pl.s' Proffer at 12.) PBMs manage approximately seventy-five percent of all outpatient prescription drug claims, and the three largest PBMs—Medco, Caremark, and Express Scripts—handle about two-thirds of those claims (or half of all retail prescriptions). (Pl.s' Proffer at 12.) Most PBMs use formularies to outline which prescription drugs are covered by a particular plan. (Pl.s' Proffer at 13.)

In turn, PBMs use Pharmacy and Therapeutics Committees ("P&T Committees") to develop formularies. P&T Committees do not conduct clinical research or review laboratory analysis of drugs, but rely on publicly available clinical information from drug manufacturers and the FDA to develop and manage formularies. (Pl.s' Proffer at 13.) The role of the PBM, for the most part, ends once a drug is added to a formulary, because individual physicians determine

[5] "While a third party payor can set its own formulary, most are established by PBMs." (Pl.s' Proffer at 13.)

whether a particular drug is better than another for an individual patient or whether the drug will be used for any particular condition. (*Id.*) Most formularies provide financial incentives, such as lower copayments, to encourage plan members to choose drugs preferred by the TPP by placing drugs in different "tiers."[6] (*Id.* at 14.) Tiered formularies specify the drugs covered but allow exceptions with increased copayments–they generally provide some level of coverage for most drugs, but "encourage selection of drugs that are most cost effective for the health plan." In 2009, eighty-nine percent of workers with an employer-sponsored prescription drug benefit were enrolled in health plans utilizing a tiered formulary. (*Id.*)

V. Plaintiffs' Claims

Plaintiffs bring claims for violations of RICO, 18 U.S.C. § 1962(c) (Count I) and § 1962(d) (Count II), state consumer protection statutes (Count III), and unjust enrichment (Count IV). (Sec. Am. Compl. ¶¶ 73, 88, 97, 150.) I respectfully recommend that the Court limits its focus to the civil RICO claims for the purposes of certifying the class because jurisdiction over the state-law claims depends on whether the federal claims are certified.[7] *See, e.g., UFCW Local 1776 and Particip. Emps. Health and Welfare Fund v. Eli Lilly & Co. ("In re*

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[6] "Formularies are considered a benefit structure component intended – in specific, narrow ways –to control or influence use of drugs by specifying which drugs are reimbursable." (Pl.s' Proffer at 13.) Formularies can "limit[] access to specific drugs or drive[] drug use to particular drugs or drug categories." (*Id.*) Most health plans use a tiered or "incentive" formulary, but the two other types are "open formularies" that cover almost all drugs with few restrictions on payment or reimbursement, while "closed formularies" restrict the types of drugs offered. (*Id.* at 14.)

[7] "The Court may elect, as Judge Weinstein did in the Zyprexa TPP class cases, to address certification of the RICO claims prior to the state consumer protection claims." (Pl.s' Reply at 10.)

Zyprexa"), 253 F.R.D. 69, 201-02 (E.D.N.Y. 2008) (deferring decision to certify state consumer fraud claims in light of certification of the RICO claim), *rev'd on other grounds*, 620 F.3d 121 (2d Cir. 2010).

RICO provides a private right of action for violations of its criminal provisions:

> Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefore in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee . . . .

18 U.S.C. § 1964(c). To prove a violation of Section 1962(c) (the "predicate offense"), a plaintiff must demonstrate an injury to business or property caused by "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496–97 (1985).[8] "For an association of individuals to constitute an enterprise, the individuals must share a common purpose to engage in a particular fraudulent common course of conduct and work together to achieve such purposes." *First Capital Asset Mgmt. v. Satinwood, Inc.*, 385 F.3d 159, 174 (2d Cir. 2004). A "racketeering activity" includes any indictable act, including mail and wire fraud. 18 U.S.C. § 1961(1)(B).[9] A pattern "requires at least two acts of racketeering activity" within a ten-year period. 18 U.S.C. § 1961(5); *McLaughlin v. American Tobacco Co.*, 522 F.3d 215, 220 (2d Cir. 2008). The compensable "injury" is "the harm caused by predicate acts sufficiently related to constitute a pattern." *Sedima*, 473 U.S. at 497.

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[8] "It shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section." 18 U.S.C. § 1962(d).

[9] The essential elements of mail and wire fraud are "(1) a scheme to defraud, (2) money or property as the object of the scheme, and (3) use of the mails or wires to further the scheme." *United States v. Shellef*, 507 F.3d 82, 107 (2d Cir. 2007). Even if the mailing itself contains no false information, the offense focuses on the scheme to defraud, and any "mailing that is incident to an essential part of the scheme satisfies the mailing element." *Schmuck v. United States*, 489 U.S. 705, 712 (1989).

To satisfy the requirement in Section 1964(c) that the injury occur "by reason of" defendant's violation, a plaintiff must show "that the defendant's violation not only was a "but for" cause of his injury, but was the proximate cause as well." *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268 (1992); *McLaughlin*, 522 F.3d at 222 ("'But for' causation is also known as . . . reliance, while proximate cause is often referred to as 'loss causation.'"). The Supreme Court has clarified that the plaintiffs themselves need not have relied on the defendants' fraud, as long as somebody relied on it. *Bridge v. Phoenix Bond*, 553 U.S. 639, 656-61 (2008) ("a plaintiff asserting a RICO claim predicated on mail fraud need not show, either as an element of its claim or as a prerequisite to establishing proximate causation, that it relied on the defendant's alleged misrepresentations"); *accord In re Zyprexa*, 253 F.R.D. at 190 ("The [*Bridge*] Court held that the person who suffered the loss need not be the one to whom the fraudulent words were directed.").

Plaintiffs allege that Aventis and its associates[10] conspired to and did misrepresent Ketek as having valid regulatory approval for broad antibiotic indications, and fraudulently marketed Ketek as safe and effective for a range of anti-microbial purposes. (Sec. Am. Compl. ¶¶ 1, 73, 88.) According to Plaintiffs, Aventis knowingly "misrepresented Ketek as having valid regulatory approval for broad indications to fight bacterial infections" and Aventis "marketed Ketek for a wide range of respiratory infection treatments even though many other safer, less-expensive medications are in fact scientifically proven as safe and effective for the treatment of drug-resistant bacterial infections." (Sec. Am. Compl. ¶ 11.) Plaintiffs allege that they paid

[10] Plaintiffs allege Study 3014 to be an association-in-fact consisting of Aventis, PPD, and Copernicus. (Sec. Am. Compl. ¶ 73.) Copernicus was selected to serve as the Independent Ethics Review Board. (Defs' Response Proffer at ¶ 16.)

for Ketek prescriptions filled by their members that their members' physicians otherwise would not have prescribed but for Aventis' fraud. (Sec. Am. Compl. ¶ 57.)

Plaintiffs now move for certification of their claims pursuant to Rule 23(b)(3) as a class consisting of

> All private, non-governmental entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse, and did pay or reimburse (for purposes other than resale), all or part of the cost of Ketek prescribed, provided, or administered to natural persons covered by such contract, policy, or plan during the period between April 1, 2004 and February 12, 2007 for uses other than community acquired pneumonia. Such entities include, but are not limited to, insurance companies, union health and welfare benefit plans, entities with self-funded plans that contract with a health insurance company or other entity to serve as a third-party claims administrator to administer their prescription drug benefits, private entities paid by any governmental entity (including a state Medicaid program), and other organizations that paid for all or part of a Ketek prescription for uses other than community acquired pneumonia between April 1, 2004 and February 12, 2007.

(Docket Entry No. 126-2, Pl.s' Post-Hr'g Subm., Ex. B, Proposed Class Certification Order, ¶ 2.)[11]

DISCUSSION

I. Class Certification Standard

Plaintiffs bear the burden of proving that all Rule 23 requirements are met by a preponderance of the evidence. *Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc.*, 546 F.3d 196, 202 (2d Cir. 2008); *In re Zyprexa*, 253 F.R.D. at 192 ("Rule 23 requirements

[11] Plaintiffs revised the proposed class definition "in an effort to clear up confusion generated in the papers and expressed by the Court about the proposed class definition." (Pl.s' Post-Hr'g Subm. 2 n.3.) Plaintiffs originally defined the class as "a class consisting of all health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit provider, including governmental entities, which paid or incurred costs for the drug Ketek between April 1, 2004 to February 1, 2007 for uses other than community-acquired pneumonia." (Sec. Am. Compl. ¶ 59.)

are threshold issues; a district court must make a ruling or a determination (not a finding) as to whether they are met."). When deciding whether to certify, "the question is not whether the plaintiffs have stated a cause of action or will prevail on the merits, but rather whether the requirements of Rule 23 are met." *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 178 (1974). Where disputed issues of fact implicate Rule 23 issues, it is the plaintiffs' burden to prove that those facts are established. *In re Initial Pub. Offering Sec. Litig. ("In re IPO")*, 471 F.3d 24, 41 (2d Cir. 2006) ("[The court must] receive enough evidence, by affidavits, documents, or testimony, to be satisfied that each Rule 23 requirement has been met.").

II. Plaintiffs Satisfy the Rule 23(a) Prerequisites

Before a class can be certified, the Rule 23 prerequisites require that:

(1) the class is so numerous that joinder of all members is impracticable,
(2) there are questions of law or fact common to the class,
(3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
(4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). None of the Rule 23(a) factors are in dispute. (Pl.s' Reply at 1.) However, this Court must independently determine that each of the 23(a) prerequisites have been met. Accordingly, as explained below, I recommend that the Court determine that the proposed class has satisfied Rule 23(a).

A. Numerosity

The class must be so numerous that joinder of all members is impracticable. *See, e.g., Central States Southeast and Southwest Areas Health and Welfare Fund v. Merck-Medco*

Managed Care, LLC, 504 F.3d 229, 244–45 (2d Cir. 2007) ("the difficulty or inconvenience of joining all members of the class make use of the class action appropriate"). Plaintiffs do not need to show evidence of exact class size. *Robidoux v. Celani*, 987 F.2d 931, 935 (2d Cir. 1993)

Plaintiffs contend that the proposed class satisfies the numerosity requirement because TPPs in the United States "number in the thousands." (Pl.s' Mem. 11; Sec. Am. Compl. ¶ 62.) Excluding the prescriptions written for community-acquired pneumonia, the indication for which it is undisputed that Ketek received proper FDA approval, "approximately 5.4 million Ketek prescriptions were written" to treat something other than pneumonia. (Pl.s' Mem. 11.) Finally, Plaintiffs contend that TPPs paid for "approximately 79% of all prescriptions written" by the beginning of the class period. (*Id.*) Defendants do not dispute numerosity. I find that the putative class is sufficiently numerous.

B. Commonality

"[A]n issue is common to the class when it is susceptible to generalized, class-wide proof." *In re Nassau County Strip Search Cases*, 461 F.3d 219, 227 (2d Cir. 2006); *see also Moore v. PaineWebber, Inc.*, 306 F.3d 1247, 1253–56 (2d Cir. 2002) (describing how the Third, Fourth, Fifth, Sixth, and Seventh Circuits generally rule for commonality in cases involving uniform fraudulent statements or misrepresentations). Rule 23(a) permits common questions of law or fact. *See, e.g., Kottler v. Deutsche Bank AG*, No. 05 Civ. 7773, 2010 WL 1221809, at *2 (S.D.N.Y. March 29, 2010) (quotations omitted) ("Plaintiffs and all Class members were allegedly victimized by a fundamentally identical scheme . . . and each Class member was similarly injured as a result of participation in that scheme . . . [t]his common factual nucleus creates common legal questions as to the claims.").

Plaintiffs contend that many factual and legal issues are common to the class. In a footnote, Plaintiffs direct the Court's attention to the "litany of the common issues" in their Second Amended Complaint. (Pl.s' Mem. at 12 n.48.) These many legal and factual issues can be summarized into two fundamental categories: (1) whether Aventis engaged in fraud and misrepresentation in marketing Ketek and obtaining regulatory approval and (2) whether Aventis is ultimately liable under RICO, various state consumer protection laws, or a theory of unjust enrichment to the TPPs. (Sec. Am. Compl. ¶ 63.) Plaintiffs argue that "the same misrepresentations and omissions would form the heart of every case" and "the trial of each TPP's claims would look virtually identical" because each TPP would use the same evidence (expert testimony provided by the same experts) to prove that Defendants (I) misrepresented Ketek's comparative effectiveness; (ii) withheld safety information about the incidence of hepatic events; (iii) misrepresented Ketek's comparative likelihood of inducing antibiotic resistance; (iv) failed to disclose that regulatory approval was invalidly obtained, and (v) damages resulted from wrong-doing. (Pl.s' Mem. at 13.) Aventis does not dispute that there are common issues among the putative class members. I therefore find that the proposed class meets the Rule 23(a) commonality requirement.

C. Typicality

"Typicality requires that the claims of the class representatives be typical of those of the class, and is satisfied when each class member's claim arises from the same course of events, and each class member makes similar legal arguments to prove the defendant's liability." *Marisol A. v. Giuliani*, 126 F.3d 372, 376 (2d Cir. 1997). Plaintiffs contend that every putative class member's cause of action arises from the same underlying course of events and that Aventis's

actions affected the TPPs in the same way. (Pl.'s Mem. at 14.) Because the class representatives and the class members all paid for Ketek or reimbursed their respective members for their prescription costs due to Aventis's conduct, Plaintiffs argue, the claims of the class representatives are typical of the claims of the class as a whole. (Sec. Am. Compl. ¶ 65.) Aventis does not dispute that the named Plaintiffs' claims are typical of those of the proposed class. Accordingly, I find that Rule 23(a)'s typicality requirement is met.

D. Adequacy of Representation

Finally, the Court must rule as to whether "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). The Court therefore examines the interests of the named Plaintiffs and look to the qualifications of Plaintiffs' counsel. *Baffa v. Donaldson*, 222 F.3d 52, 60 (2d Cir. 2000). "A class representative must be part of the class and possess the same interest and suffer the same injury as the class members." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625–26 (1997) ("[Determining adequacy] serves to uncover conflicts of interest between named parties and the class they seek to represent.). Only a fundamental conflict will defeat the adequacy requirement. *Schwab v. Philip Morris*, 449 F. Supp. 2d 992, 1107 (E.D.N.Y. 2006), *rev'd on other grounds by McLaughlin*, 522 F.3d 215 ("representative plaintiffs must not have interests that are antagonistic to or in conflict with those of the class as a whole").

Plaintiffs' attorneys are qualified and experienced in conducting nationwide consumer fraud class actions. *See, e.g., In re Zyprexa Prods. Litig.*, 253 F.R.D. at 200; *In re Neurontin Mktg. and Sale Practices Litig.*, 244 F.R.D. 89, 108 (D. Mass. 2007). Aventis does not dispute counsels' qualifications or expertise. Therefore, the fourth Rule 23(a) factor concerning

counsels' adequacy is met. As for the named plaintiffs, the SBA Fund, the NEC Fund, and the ASD Fund submit that they are knowledgeable of and have been active in this litigation as demonstrated by their reviewing the complaint and gathering materials to respond to document requests, among other things. (Pl.s' Mem. at 16-17.) Aventis deposed Errol Ogman, a representative of the SBA Fund, on January 6, 2010, and Harry R. Dow from the NEC Fund on January 7, 2010. (Pl.s' Proffer at 94-95, nn.529, 530.) The proposed class representatives have suffered the same injury as the putative class members, namely, paying all or a part of the cost of prescriptions of Ketek for its beneficiaries during the class period. (Pl.s' Proffer at 93.) As with the other Rule 23(a) prerequisites, Aventis does not dispute that the plaintiffs can adequately represent the proposed class. Accordingly, I find that the adequacy of representation is established.

III. Rule 23(b) Requirements[12]

Plaintiffs seek damages under Rule 23(b)(3), under which a class may be certified if:

> the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy.

Fed. R. Civ. P. 23(b)(3); *see Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 161 (1982) (requiring that district courts conduct a rigorous analysis of whether Rule 23 prerequisites are met before certifying a class). The Second Circuit has defined a "rigorous analysis" as "made only if the

[12] Despite the allegation seeking "equitable relief and damages pursuant to Federal Rule[s] of Civil Procedure 23(b)(2) and 23(b)(3)," the Court assumes that Plaintiffs seek to certify only a Rule 23(b)(3) class because a Rule 23(b)(2) injunctive class is not mentioned in the motions for class certification. (Sec. Am. Compl. ¶ 60.)

judge resolves factual disputes relevant to each Rule 23 requirement and finds that whatever underlying facts are relevant to a particular Rule 23 requirement have been established . . . [i]n making such determinations, a district judge should not assess any aspect of the merits unrelated to a Rule 23 requirement . . . ." *In re IPO*, 471 F.3d at 41 ("[This] obligation is not lessened by overlap between a Rule 23 requirement and a merits issue, even a merits issue that is identical with a Rule 23 requirement.").[13]

A. Predominance

The crux of the parties' dispute on class certification is whether common questions of law or fact predominate on the issue of causation, or whether causation must be proved through individualized evidence. (Pl.s' Mem. at 2.)

1. Legal Standards

To recover damages under RICO, a plaintiff must prove "(1) a substantive RICO violation under § 1962; (2) injury to the plaintiff's business or property, and (3) that such injury was by reason of the substantive RICO violation." *City of New York v. Smokes-Spirits.com*, 541 F.3d 425, 439 (2d Cir. 2008), *overruled on other grounds by Hemi Group v. City of New York*, – U.S. –, 130 S. Ct. 983 (2010). To prove injury by reason of a RICO violation, a plaintiff must demonstrate that the violation caused his injury in two ways: First, that the defendant's conduct

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[13] The Court recognizes that predominance is more demanding than commonality and typicality. *Amchem*, 521 U.S. at 623; *In re Visa Check/Master Money Antitrust Litig.*, 280 F.3d 124, 136 (2d Cir. 2001) ("[T]o meet the predominance requirement of Rule 23(b)(3), a plaintiff must establish that the issues in the class action that are subject to generalized proof, and thus applicable to the class as a whole, . . . predominate over issues that are subject only to individualized proof.") (quotation marks and citations omitted); *accord Moore*, 306 F.3d at 1252 ("Class-wide issues predominate if resolution of some of the legal or factual questions that qualify each class member's case as a genuine controversy can be achieved through generalized proof.").

was the proximate cause of his injury – "there was a direct relationship between the plaintiff's injury and the defendant's injurious conduct." *First Nationwide Bank v. Gelt Funding Corp.*, 27 F.3d 763, 769 (2d Cir. 1994); Second, that "but for" the defendant's conduct he would not have been injured. *Holmes*, 503 U.S. at 268.

Although a plaintiff's direct reliance is not a formal element of her RICO claim, there is no question that in cases such as this a plaintiff must allege and prove at least third-party reliance as part of the chain of causation. *In re Zyprexa Prods. Liab. Litig.*, 620 F.3d 121, 133 (2d Cir. 2010). Because reliance is a necessary part of the causation theory Plaintiffs must be able to prove it through common evidence in order to obtain class certification.

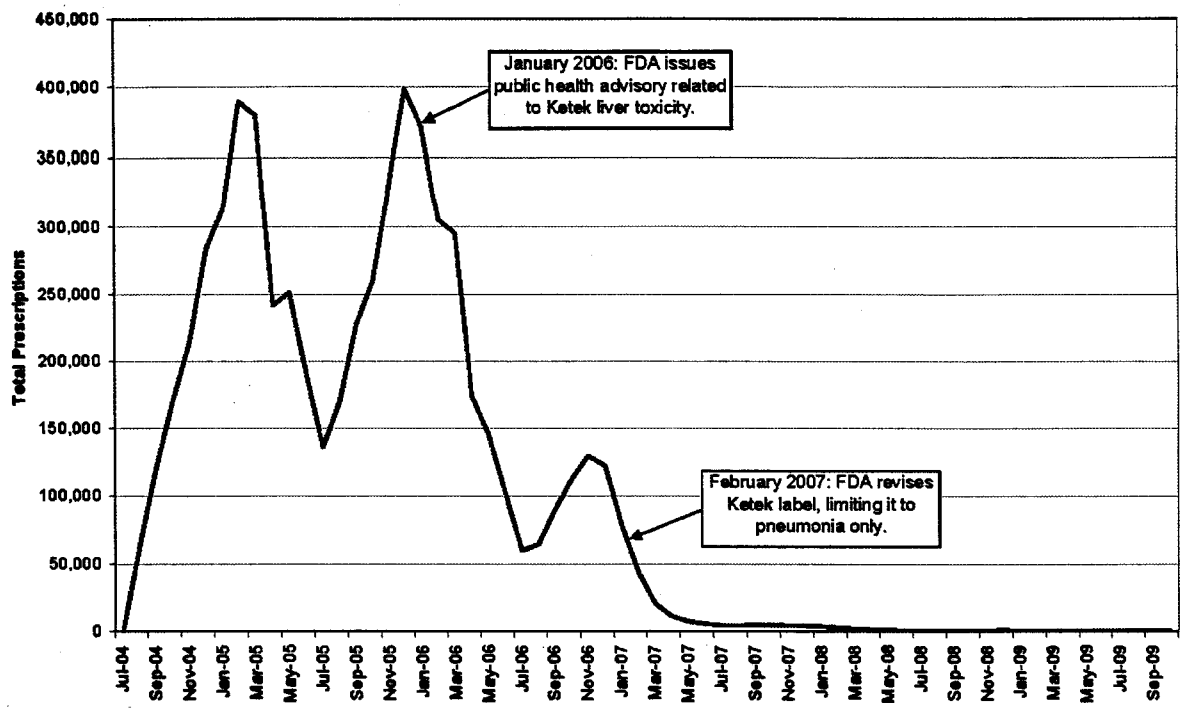
2. Plaintiffs' Contentions[14]

Plaintiffs contend that causation can be proved with common evidence. Plaintiffs argue that Aventis's misrepresentations and omissions were a substantial cause of TPP payments for Ketek, and can be proved by market data demonstrating that nearly all Ketek prescriptions stopped in mid-2006 once the true efficacy and safety risks of Ketek were made known to the market, evidence common to all putative class members. (Pl.s' Mem. at 22.) Plaintiffs also points to common evidence of the applicable standard of care for prescribing Ketek and that "within months" after the truth about Ketek's safety and efficacy was revealed, Ketek had been either restricted or removed from over three-quarters of all TPP formularies. *Id.* According to Plaintiffs, "[o]nce the truth about Ketek's safety risks began to emerge, prescriptions and sales of

[14] This represents a summary of Plaintiffs' major factual and legal contentions, and does not purport to discuss and analyze each and every assertion in their many written submissions in support of their motion for class certification. Nevertheless, I reviewed and analyzed all of Plaintiffs' submissions and arguments before rendering a recommendation on their motion for class certification.

Ketek plummeted, without ever reversing course," and this "monotonic decline" proves that Aventis's conduct caused the third-party physicians' decisions to prescribe Ketek and the TPPs' decisions to include Ketek in formularies.

To prove that physicians prescribed Ketek based predominately on Aventis's misrepresentations, Plaintiffs rely heavily on statistical evidence proffered by Meredith Rosenthal, Ph.D, a health care economist, that illustrates the number of Ketek prescriptions filled from July 2004 through September 2009:



This chart shows Ketek quarterly sales over time for all pharmacies nationwide, (Transcript of June 15, 2010 Hearing ("Tr. at 106:4-107:12"), and is based on data provided by IMS Health, "a consulting company and data aggregation firm that works broadly in" the pharmaceutical industry and electronically records data on prescription drug sales from retail pharmacies (Tr. at

106:14-16). It is apparently undisputed that "these data are nationally representative of retail pharmacy sales for Ketek." (*Id.* at 106:24-25.)

As can be seen from the chart, Ketek prescriptions rose steadily from its launch in July 2004 through the winter of 2004-2005, then dropped precipitously during the spring and summer of 2005. Ketek prescriptions then rose again from July/August 2005 to January 2006, then again dropped precipitously in the winter of 2005-2006. After a brief "uptick" in sales from July 2006 through November 2006, sales dropped again and never returned. (Pl.s' Mem. at 14–15.)

Dr. Rosenthal explains the spring and summer 2005 decline in Ketek prescriptions as due to the normal cyclical decline in bacterial infections during the summer months.[15] Dr. Rosenthal attributes the precipitous drop in Ketek prescriptions beginning in the winter 2005–2006 as due to (1) the FDA's January 2006 public health advisory regarding Ketek's liver toxicity, (2) the FDA's June 2006 strengthening of Ketek's label to include the risk of liver damage, and (3) the FDA's February 2007 withdrawal of approval for two of Ketek's three indications. According to Dr. Rosenthal

> physicians clearly stopped prescribing Ketek after the first disclosures, the public health advisory of January 2006 and subsequent disclosures over the period of 2006/early 2007. This decline is extremely precipitous in my experience compared to other products that I have looked at in litigation and research in response to other market factors, like changes in competition or even other kinds of safety events that have affected market share. I have never seen a product's sales decline this rapidly and completely. In my opinion, the only plausible explanation for this decline in sales is the new information that was allegedly suppressed by the defendant.

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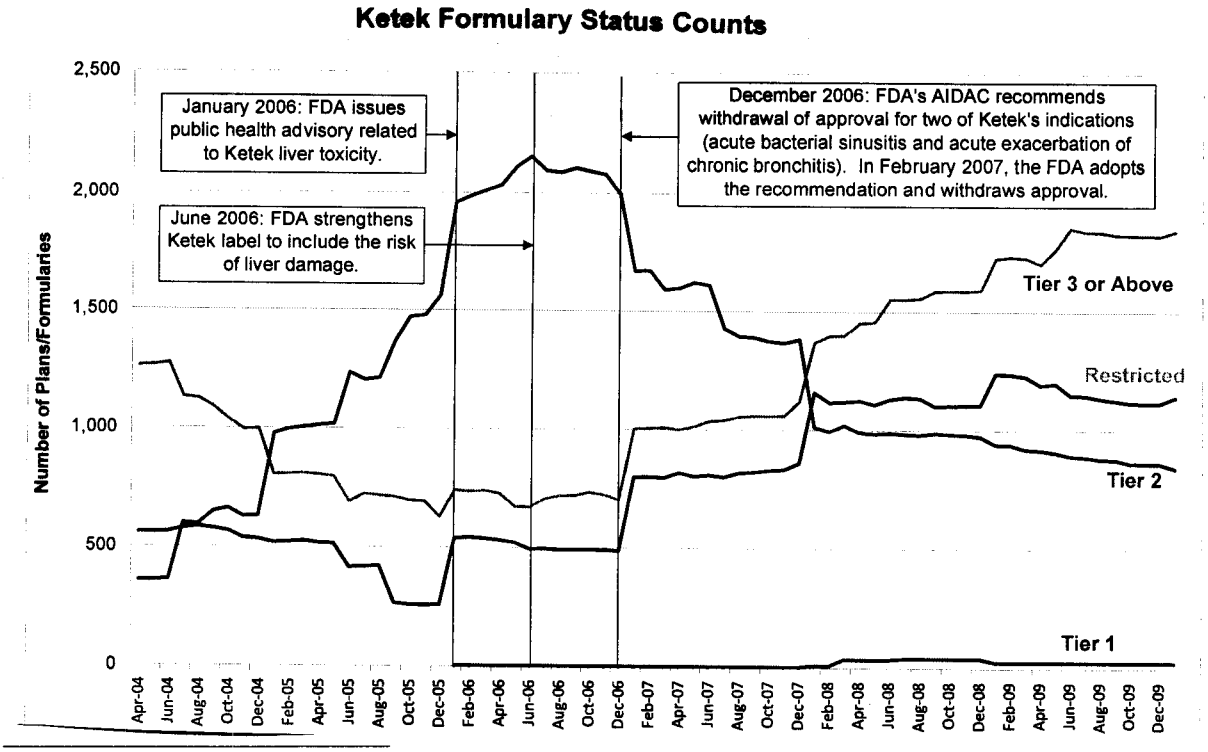
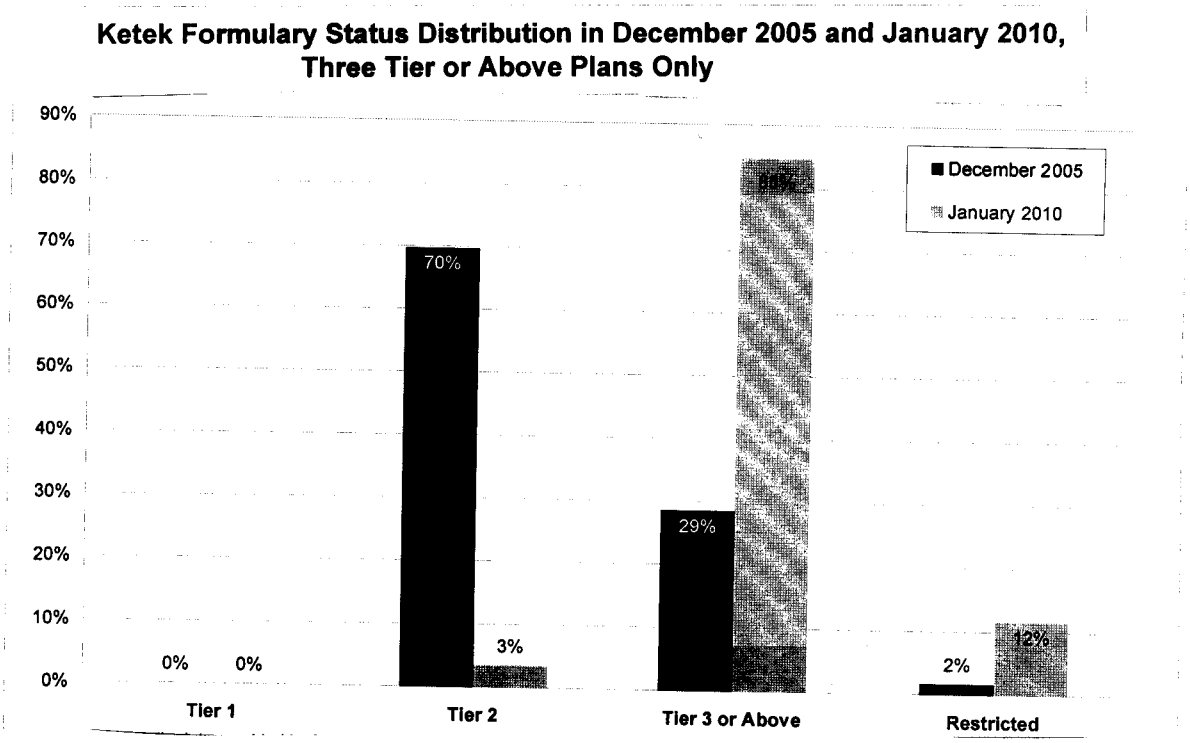
[15] "Because it is a drug that is used for infections of a kind that people essentially get into the winter months, the seasonality of this drug, you will see, will peak up going into the end of the fall or into the winter and then will essentially peter out come the end of spring, and you'll see that normally for all drugs." (Tr. 11:1-4; *see also* Tr. 107:6-12.)

(Tr. at 105:18-106:4.; *see also id.* at 109:17-110:6 (FDA disclosures the predominant, if not only, factor in drop of Ketek sales).) In sum, Plaintiffs argue that this "[c]ommon evidence demonstrates that Aventis's misrepresentations and non-disclosures . . . were a substantial contributing factor . . . [of] substantially all non-CAP purchases of Ketek." (Pl.s' Reply at 5.)[16] Put another way, once the truth about Ketek was made known, virtually all non-CAP prescriptions for Ketek ceased.

Dr. Rosenthal also cites to common statistical evidence for the proposition that TPPs' formulary placement was adversely effected by Aventis' misinformation:



[16] Notably, Dr. Rosenthal was not asked to and did not conduct a regression or other "cause-and-effect analysis relating to the various factors that could have led to the decline in Ketek's sales" and "which might be the kind of analysis that an economist would undertake." (Tr. 138:14-16.) At no time did Dr. Rosenthal say that a regression analysis could not be performed due to the lack of data or some other problem, or that a regression analysis would be inappropriate in this case. Basically, Dr. Rosenthal opined that in light of her knowledge and experience as a health care economist, there can be only one explanation for the monotonic decline in Ketek sales – the revelation of Aventis's fraud. (Tr. 128:8-130:11, 136:12-144:15.)



The data for these charts was aggregated by MediMedia, "another data aggregation and consulting company that works with pharmaceutical manufacturers and others to look at the marketplace, formulary placement being one of the many important factors that determine market share." (Tr. at 115:22-116:1.)

According to Dr. Rosenthal, these chart demonstrate "a steady downward trend in Ketek's formulary placement from the point of disclosure of the information about Ketek's safety risks that were allegedly omitted or suppressed." (Tr. at 115:16-19.) In other words, once the truth about Ketek's efficacy and safety risks was made known, there was "an almost wholesale shift in formulary status" from more-preferred (tier two) to less-preferred (tier three or higher) positions. (*Id.* at 116:10-11.) At the end of the period, Ketek's formulary status was tier three or higher in nintey-seven percent of TPP formularies across the country. *Id.* at 116:11-13; see also discussion at *id.* 116:4-119:20.

Plaintiffs also rely heavily on the reports and testimony of their medical experts, who collectively opined: (1) physicians live by the creed "do no harm," and always consider patient safety in making treatment decisions; (2) physicians place substantial reliance on the FDA label and on information from the FDA; (3) Ketek showed no superiority over other antibiotics; and (4) physicians did not have information about Ketek's increased risks of serious possibly-related adverse events until the FDA's January 2006 public health advisory regarding Ketek's liver toxicity. (Plaintiffs' Post-Hearing Submission in Further Support of the Motion for Class Certification ("Pl.s' Post-Hrg. Br.") at 1-4 (citations to briefs, declarations and record evidence omitted).) Plaintiffs place particular reliance on the opinion of Dr. David A. Neumeyer, their board certified internist, who contends Ketek

> would not have been prescribed for acute bacterial sinusitis or acute exacerbation of chronic bronchitis beginning in 2004 had the risks of severe side effects, including hepatic events, and the lack of superior effectiveness against drug-resistant pathogens been made clear. The risk benefit profile for using [Ketek] is clearly outweighed by the relatively benign nature of ABS and AECB, along with safe and inexpensive alternative antimicrobial treatment options. Similarly, the use of [Ketek] would have declined significantly, had it not been available on formularies or been considered a non-preferred drug.

(Declaration of David A. Neumeyer, M.D., dated January 15, 2010, at 8.) In other words, Dr. Neumeyer contends that prescribing Ketek was contrary to the applicable standard of care, and this is evidence common to every physician who ever prescribed Ketek.

3. Defendant's Contentions[17]

Aventis contends that neither but-for nor proximate causation can be proven by common evidence because physicians' decisions to prescribe Ketek (but-for cause) are inherently

[17] Again, I will not recount here all of Aventis' factual and legal contentions, but only mention those which I find important to the critical determination of whether causation can be proved with common evidence.

individual and based on a multitude of factors, and P&T Committees' decisions to include Ketek in the TPP's formularies (proximate cause) vary greatly pursuant to differing criteria. (Defendants' Memorandum Of Law In Opposition to Plaintiffs' Motion For Class Certification at 9-34 ("Defs' Opp. Mem.").)

Pointing to admissions from Plaintiffs' own experts, Aventis argues that aside from a drug maker's representations regarding efficacy and safety, there are a number of general and *individual, patient-specific* factors that the physicians consider in deciding what antibiotic to prescribe to a patient: age, gender, possibility of pregnancy, drug allergies, frequency of the type of infection presented, success of prior courses of treatment, concurrent medications, concurrent illnesses, family history, drug compliance tendencies, patient preferences, side effects from previously administered antibiotics, likelihood of antibiotic resistance, and the profile of antibiotic resistence in the region. "Only after considering all of these factors will a physician choose the antibiotic most appropriate for the patient he or she is treating." (Defs' Opp. Mem. at 24.) Using its own expert physician, Dr. Sanjay Sethi, Aventis also vigorously disputes Dr. Neumeyer's opinion that prescribing Ketek was contrary to the standard of care. According to Dr. Sethi, Ketek was, and still is, an appropriate antibiotic for a physician to prescribe after taking into account the individual, patient-specific factors identified above. (Tr. 221:24-245:15.) Thus, Aventis argues, Plaintiffs cannot prove through common evidence that had Ketek's efficacy and safety risks been properly disclosed, each and every Ketek prescription for which they paid would not have been written.

Aventis disputes Dr. Rosehthal's statistical evidence, contending that it assumes that if fraud is proven then "*every* prescription for a non-CAP indication caused the class members

injury in an amount equal to the amounts they paid for the Ketek prescriptions." (Defs' Opp. Mem. at 12 (emphasis in original).) Aventis also criticizes Dr. Rosenthal's methodology in that it did not attempt to account for other possible causes of the decline in Ketek sales: cessation of marketing and promotion; cessation of rebates to PMBs; entry of generics into market; or increase in negative marketing of Ketek by Aventis's competitors. (*Id.* at 29-30.)

Aventis argues further that Dr. Rosenthal's analysis is faulty in that it incorrectly assumes that every Ketek prescription that was not written for CAP was written for either AECB or ABS. "This assumption ignores the fact that physicians are legally allowed to and often did prescribe Ketek for an indication for which Ketek was not approved." (Defs' Opp. Mem. at 12, n.7, citing Ex.8: Rosenthal Rep. ¶ 40.) Plaintiffs themselves admit that physicians frequently prescribe antibiotics for off-label uses[18] and proffered that "47.7% of Ketek prescriptions were written for indications that were [n]ever approved by [the] FDA and were not the subject of the fraudulent marketing activities alleged by Plaintiffs." (Defs' Opp. Mem. at 12 n.7.) Accordingly, Aventis argues that Plaintiffs cannot prove by common evidence that every Ketek prescription not written for CAP was written for either AECB or ABS, the two other indications for which Ketek originally received FDA approval. (Defs' Opp. Mem. at 12 n.7.)[19]

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[18] For example, although antibiotics are typically used to treat respiratory tract infections, acute sinusitis typically occurs as a viral infection and antibiotics are therefore typically ineffective against it. "In the United States, physicians nonetheless prescribe antibiotics to 85–98% of such patients, and a wide variety of anti-infective therapies used to treat acute sinusitis have been available for several years." (*Id.* at 18–19.)

[19] In addition, Aventis points to an article relied upon by one of Plaintiffs' experts which indicates that even after Ketek's indications for AECB and ABS were withdrawn, 12.8% of all Ketek prescriptions were written for AECB and 34.1% for ABS; further evidence of off-label prescriptions. According to Aventis, these percentages are almost identical for the period before the indications for AECB and ABS were withdrawn, thus indicating that not every physician stopped prescribing Ketek for AECB and ABS after the indications were withdrawn. (Def's

Aventis contends further that Plaintiffs cannot prove proximate cause by common evidence because regardless of the alleged fraud, each P&T Committee considers different information and decides to approve drugs for inclusion on a formulary in different ways. (Defs' Opp. Mem. at 14.) Aventis contends that to qualify for class certification, Plaintiffs must prove that Aventis's alleged omissions and misrepresentations caused the P&T Committees to approve the use and reimbursement of Ketek differently than they would have absent Aventis's conduct. (*Id.*) If a P&T Committee did not rely on Aventis's alleged fraud in deciding Ketek's formulary placement, then Plaintiffs cannot prove proximate cause. (*Id.* at 13.)[20]

While not directly attacking Dr. Rosenthal's proffered statistics concerning Ketek's formulary placement over time, Aventis disputes Plaintiffs' evidence concerning the TPP's restriction or removal of Ketek from their formularies, contending that TPPs' coverage decisions differ greatly. For example, the PBM that provides formulary services to the ASD Fund, one of the named plaintiffs, continues to list Ketek as a Tier 2 preferred position in their three-tier formulary even after the FDA removed its AECB and ABS indications. (Defs' Opp. Mem. at 18.) The SBA Fund, another named plaintiff, has also maintained coverage for Ketek despite the FDA adverse actions.[21] (*Id.* at 19.) Aventis contends that these are just two examples of PBMs

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Opp. Mem. at 25, n.21.)

[20] Aventis notes that Dr. Rosenthal "was not retained to undertake a 'cause and effect analysis,'" and admitted at her deposition that her statistical analysis "is not intended to show that the events listed in [figure 1] (the February 2006 public health advisory and the February, 2007 withdrawal of two of Ketek's indications) *caused* any drop in Ketek sales." (Defs' Opp. Mem. at 28 (emphasis in original).)

[21] Under the SBA Fund's plan, nearly all FDA-approved drugs are covered, and the plan does not use a tiered incentive system to distinguish among preferred, non-preferred, or generic drugs. (Defs' Opp. Mem. at 19.)

and TPPs who have not made any changes in Ketek's formulary status since information about Ketek's safety and efficacy were revealed. (*Id.*) Accordingly, Aventis argues that Plaintiffs cannot show by common evidence that P&T Committees uniformly relied on Aventis's allegedly fraudulent conduct when making formulary decisions for Ketek.

4. Causation Cannot Be Proved By Common Evidence

The Court need not tarry any longer on the parties' factual and legal arguments on whether but-for or proximate causation can be proved through common evidence because the Court of Appeals for the Second Circuit recently answered these questions in the negative in a similar TPP case. *In re Zyprexa Prods. Liab. Litig.*, 620 F.3d 121.[22]

In *In re Zyprexa*, TPP plaintiffs sought to recover RICO damages from a drug manufacturer under two distinct theories, the "excess price theory" and the "quantity effect theory." Under the "excess price theory," the TPPs sought to recover the excess price they paid for a drug as a result of the defendant's "excess claims of utility" and "disavowal of adverse secondary effects." In other words, had the company been truthful about the utility and adverse secondary effects, the price for the drug would have been less, whether through normal market forces, or through the TPP's ability to negotiate a lower price.[23] Under the "quantity effect theory," a TPP pays for more prescriptions than it otherwise would have in absence of the fraud because had the truth about the drug been made known, P&T Committees would not have put the drug on formularies and physicians would not have prescribed the drug for their patients. The

[22] Plaintiffs' counsel also represents the plaintiffs in *In re Zyprexa*. The Second Circuit's decision was handed down after the parties here had briefed and argued the instant motion for class certification.

[23] Plaintiffs here do not assert the excess price theory.

Second Circuit ultimately held that causation under either theory, whether but-for or proximate, *could not* be proved using common evidence.

With respect to the quantity effect theory, which is also asserted here, the Court noted that it:

> suffers from many of the same faults as the excess price theory. An examination of plaintiffs' theory of causation makes this apparent. Dr. Harris, plaintiffs' expert, estimated damages under the quantity effect theory by assuming that the decline in the number of Zyprexa prescriptions following the label change and "Dear Doctor" letter in 2003 and 2004 was due almost entirely to a decrease in the number of off-label Zyprexa prescriptions. Dr. Harris then assumed that, but for Lilly's alleged misrepresentations, sales of Zyprexa would never have risen above the number of sales in 2006, after more accurate information about Zyprexa's side effects became public. Dr. Harris thus postulated that every prescription above the number of prescriptions written in 2006 was an "excess" prescription, and plaintiffs should recover the full cost of every excess prescription.
>
> Having removed the variable of price, the chain of causation is in one sense simpler: TPPs place Zyprexa on their formularies as approved drugs, Lilly distributes misinformation about Zyprexa, physicians rely upon the misinformation and prescribe Zyprexa, and TPPs pay for too many Zyprexa prescriptions.
>
> *The nature of prescriptions, however, means that this theory of causation is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof.* Plaintiffs argue that "the ultimate source for the information on which doctors based their prescribing decisions was Lilly and its consistent, pervasive marketing plan." Lilly was not, however, the only source of information on which doctors based prescribing decisions. An individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing Zyprexa, and the physician's knowledge regarding the side effects of Zyprexa are all considerations that would have been taken into account in addition to the alleged misrepresentations distributed by Lilly.
>
> Furthermore, additional variables interfere further with plaintiffs' theory of causation. As the district court noted, the evidence showed that at least some doctors were not misled by Lilly's alleged misrepresentations, and thus would not have written "excess" prescriptions as identified by the plaintiffs. *This makes general proof of but-for causation impossible.*

* * *

> All of these variables show that the quantity effect theory is no more demonstrable with generalized proof than the excess price theory. *Plaintiffs cannot use generalized proof when individual physicians prescribing Zyprexa may have relied on Lilly's alleged misrepresentations to different degrees, or not at all, when some excess prescriptions may not have actually caused loss, given the likelihood of substitute prescriptions for other drugs, and when different TPPs may have paid for different "excess" quantities of prescriptions.* We therefore decline to affirm class certification based on the quantity effect theory.

In re Zyprexa Prods. Liab. Litig., 620 F.3d at 134-135 (emphasis added). *See also In re Neurontin Mktg. & Sales Practices Litig.*, 677 F. Supp. 2d 479, 494 (D. Mass. 2010) ("[T]rial courts have almost uniformly held that in a misrepresentation action involving fraudulent marketing of direct claims to doctors, a plaintiff third-party payor or class must prove through individualized evidence that the misrepresentation caused specific physicians, third-party payors, or consumers to rely on the fraud, and cannot rely on aggregate or statistical proof.") (emphasis added). The same result should follow here.

Plaintiffs argue in an unauthorized submission that the Court of Appeals decision in *In re Zyprexa* "does not apply to the case currently before this Court and will not aid in the disposition of this litigation." (Docket No. 131 at 1.) First, Plaintiffs point to differences between the common proof, and factual and legal arguments offered in *In re Zyprexa* and this litigation. (*Id.* at 1-3.) Second, Plaintiffs contend that the Second Circuit's rejection of common evidence to prove the quantity effect theory is "purely dicta." (*Id.* at 4, n.1). Both arguments are misplaced.

First, while there are differences between the underlying facts, arguments and purported common evidence offered in this and *In re Zyprexa*, those differences are immaterial. Plaintiffs may be correct that their proffered common evidence shows that some, or perhaps many

physicians who prescribed Ketek *considered* uniform misinformation supplied by Aventis.[24] That evidence does not show, however, that all, most, or even some of those physicians prescribed Ketek to their patients *because of* Aventis's misinformation. Plaintiffs' entire argument ignores the individualized nature of the prescription-making process, and its prohibitive effect on proving but-for causation with common proof. As emphasized by the Court of Appeals in Zyprexa, the inherent nature of the prescription process simply does not lend itself to common proof of causation. As discussed above, physicians prescribe medications to their patients based on a variety of factors, which may or may not include information provided by drug companies. Based on the common evidence Plaintiffs proffer there is simply no way to determine whether all, or even most, of the physicians who previously prescribed Ketek for their patients based their decisions on Aventis's purported misinformation.[25] Indeed, the fact that Ketek sales plummeted "monotonically" after the FDA public health advisory and removal of indications for AECB and ABS does not mean that prior thereto any physician based her decision

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[24] That information includes (1) Ketek's FDA approval, procured by Aventis by allegedly fraudulent means, and (2) the marketing of Ketek as safe and efficacious compared to other drugs without the risk of adverse side-effects.

[25] Because I find this issue to be dispositive, I decline to issue a detailed recommendation on Aventis' argument that Plaintiffs also cannot prove injury with common evidence. (Def's Opp. Mem. at 10-12.) Were I called upon to issue such a recommendation, I would recommend that they could not. The inescapable fact is that even if physicians would not have prescribed Ketek had they known of its true efficacy and safety risks, they would have prescribed some other antibiotic, which may have cost the same or more than Ketek. *See In re Zyprexa Prods. Liab. Litig.*, 620 F.3d at 135 ("Plaintiffs cannot use generalized proof . . . *when some excess prescriptions may not have actually caused loss*, given the likelihood of substitute prescriptions for other drugs, and when different TPPs may have paid for different "excess" quantities of prescriptions." (emphasis added)) Based on the language from *In re Zyprexa* quoted above, Plaintiffs' argument that their "but-for world is no purchases of Ketek for any non-CAP use – period" (Pls' Reply at 8), is simply wrong. Even their own experts admit as much. (Abramson Dep. at 39-41, Neumeyer Dep. at 165, 184-85).

to prescribe Ketek on Aventis's fraud. It may well be that physicians prescribed Ketek based on factors other than Aventis's fraud, and then later decided to discontinue prescribing Ketek once they knew of the true efficacy and health risks. Plaintiffs' proffered common evidence simply does not prove reliance.

Second, Plaintiffs are simply wrong that the Second Circuit's rejection of aggregate proof of causation for the quantity effect theory is "purely dicta." Although the *Zyprexa* plaintiffs appeared to have abandoned the quantity effect theory in the District Court, as the Circuit properly noted, they "resurrect[ed] the quantity effect theory of injury" on appeal. *In re Zyprexa*, 620 F.3d at 134. Indeed, in their opposition brief in the Circuit, Plaintiffs repeatedly argued the quantity effect theory.[26] Thus, Plaintiffs' argument that "[t]he quantity theory was not before the Court *in any form*: the district court had not advanced the theory and *the parties did not brief or argue it*" is patently false. (Docket No. 131 at 4 n.1 (emphasis added).) In any event, even were this aspect of *In re Zyprexa* considered dicta, the reasoning is sound and persuasive, and should be followed. *Patsy's Italian Restaurant, Inc. v. Banas*, 508 F. Supp. 2d 194, 209 (E.D.N.Y. 2007) ("as a general principle, a federal district court is required to give great weight to the pronouncements of its Court of Appeals, even though those pronouncements appear by way of

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[26] *See In re Zyprexa*, 09 Civ. 0222, Brief for Plaintiffs-Appellees at 30 (defendant's "Fraud Caused [plaintiffs] to Pay for Too Many Zyprexa Prescriptions"), 36 (arguing that plaintiffs paid "too much *for too many* Zyprexa prescriptions), 38 (arguing that "the district court found [defendant's] scheme *caused an increased number of Zyprexa prescriptions*"), 47 (defendant's "scheme was designed to impact the number of prescriptions written, *elevating unit sales*"), 49 (defendant's "Fraudulent Scheme Affected All Payers by *Inflating the Number of Zyprexa Prescriptions Written*"), 56 ("[a]ssuming cause-in-fact is established at trial for increased launch price and/or *increased prescriptions in the aggregate*"), 60 (defendant's "fraud also caused [plaintiffs] to pay for too many Zyprexa prescriptions") and ("a jury can evaluate [plaintiffs' expert's] *quantity-based damages model*, common to all class members") (emphasis added)).

dictum.") On this record, and absent any controlling precedent directly on point and to the contrary, there is simply no reason to decide this motion for class certification differently than the Court of Appeals decided in *In re Zyprexa*.[27]

B. Superiority

Rule 23(b)(3) requires Plaintiffs to show that "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). However, because common issues do not predominate over individualized questions, the Court need not address this question. *See McLaughlin*, 522 F.3d at 222 ("We need not address whether a class action is a superior method of adjudicating plaintiffs' claims" because prior determination that common questions did not predominate).

CONCLUSION

For the reasons explained above, I respectfully recommend that class certification be denied. Any objections to this Report and Recommendation must be filed with the Clerk of the Court and the Honorable Sandra L. Townes within fourteen days of receipt hereof.

[27] Because *In re Zyprexa* forecloses proof of but-for causation with common evidence, the Court need not determine whether proximate cause (TPP formulary placement) can be proved using common evidence. If, however, I were called upon to render such a recommendation, I would recommend that proximate cause cannot be proved using common evidence. As Aventis argus, each TTP or PCM determine drug placement in formularies differently, and cannot be established with common evidence.

Failure to file timely objections may waive the right to appeal the District Court's Order. *See* 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72.

Dated: February 16, 2011
Brooklyn, New York

Ramon E. Reyes Jr.
Ramon E. Reyes, Jr.
United States Magistrate Judge